(ii) Citizen petitions under §10.30 of this chapter;

(iii) Petitions for reconsideration under §10.33 of this chapter;

(iv) Petitions for stay under §10.35 of this chapter; or

(v) Requests for advisory opinions under §10.85 of this chapter.

(3) With respect to any matter delegated to the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy under paragraph (f) of this section, the Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized to perform the function of the Commissioner of Food and Drugs under §§10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under §10.206(g) and (h) of this chapter. This authority may not be further redelegated.

(4) The Senior Associate Commissioner for Policy, Planning, and Legislation and the Associate Commissioner for Policy are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. This authority may be further redelegated.

(g) The following officials are authorized to perform all of the functions of the officials under them in their respective offices, and this authority may not be further redelegated:

(1) Senior Associate Commissioner;

(2) Deputy Commissioner for International and Constituent Relations;

(3) Deputy Commissioner for Management and Systems; or

(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions (under 21 U.S.C. 379h(d)) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. This authority may not be further redelegated. (See §5.101 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

(2) The Deputy Commissioner for Management and Systems and the Director, Office of Financial Management are authorized to perform the functions of the Commissioner under 21 U.S.C. 379h(d)(1)(C), as amended, to waive or reduce prescription drug user fees in situations where he/she finds that ''the fees will exceed the anticipated present and future costs.'' This authority may not be further redelegated.

(3) The Deputy Commissioner or, in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. This authority may not be further redelegated.

(i) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under 35 U.S.C. 156(d)(2)(B)(ii), as amended, relative to patent term extensions. This authority may not be further redelegated.

(j) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983; 56 FR 36001, July 30, 1991; 57 FR 12875, Apr. 14, 1992; 58 FR 17095, Apr. 1, 1993; 59 FR 14549, Mar. 29, 1994; 61 FR 2414, Jan. 26, 1996; 62 FR 923, Jan. 7, 1997; 62 FR 48757, Sept. 17, 1997; 63 FR 41960, Aug. 6, 1998; 64 FR 59618, Nov. 3, 1999; 65 FR 34960, June 1, 2000]

§5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same

officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Deputy Commissioner for International and Constituent Relations, and the Deputy Commissioner for Management and Systems.

(2) The Senior Associate Commissioners, the Associate and Deputy Associate Commissioners, and the Chief Counsel and Deputies.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner.

(4) The Executive Assistant to the Commissioner, Office of the Commissioner.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management, ORA.

(iv) The Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, ORA.

(v) The Director, FDA History Staff, ORA.

(6)(i) The Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(ii) The Director, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(iii) The Chief, Dockets Management Branch, Division of Management Programs, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(7)(i) The Associate Commissioner for Public Affairs, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

(ii) The Director, Freedom of Information Staff, Office of Public Affairs, Office of the Senior Associate Commissioner, Office of the Commissioner.

(8)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Office of Compliance, CBER.

(iv) The Director of Congressional and Public Affairs Staff, Office of the Center Director, CBER.

(v) The Chief, Surveillance and Policy Branch and Consumer Safety Officers, Office of Compliance, CBER.

(9)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Special Nutritional, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Premarket Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(xiii) The Director, Office of Food Labeling, CFSAN.